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APR 12 1991

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: Dekantel Microflex
Ophthalmic Suture

FDA Docket No. 91E-0091

Dear Mr. Wilson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,621,638 filed on February 22, 1991, by Pfizer Hospital Products Group, Inc. under 35 USC § 156. The medical device claimed by the '638 patent is the Dekantel Microflex Ophthalmic Suture.

On April 9, 1991, the PTO mailed a letter to the FDA which provided notice under 35 USC § 156 (d) (2) (A) and requested a determination of the applicable review period. Further review of the application and in particular your letter of April 2, 1991, shows, however, that the '638 patent may not be eligible for extension of the patent term under 35 USC §156 because the Dekantel Microflex Ophthalmic Suture was not approved under section 515 of the Federal Food, Drug, and Cosmetic Act, but instead received permission to market under section 510 (k). Accordingly, subject to further review of the application, the April 9, 1991, notice under 35 USC § 156 (d) (2) (A) and request for determination of the applicable review period are hereby rescinded. Until further notice, no action on your part should be taken under 35 USC § 156 (d) (2) (A).

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: John L. LaPierre
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